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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,045	01/11/2005	Daniel Rachlin	336-1102US	6611

23429 7590 03/26/2007
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EXAMINER

BOR, HELENE CATHERINE

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Application No.

10/521.045

Applicant(s)

RACHLIN ET AL.

Examiner

Helene Bor

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/11/2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 10/27/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1-7, 9, 11-13, 15 & 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata'149 et al. (US Patent No. 5,078,149).

Claim 1: Katsumata'149 teaches an interface device for use with an ultrasound imaging system having a scan head with at least one transducer (Abstract). While Katsumata'149 does not specifically mention for use with a high frequency ultrasound imaging system, Katsumata'149 does teach the use of the system to be adapted for various ultrasound probes (Col. 11, Line 17-23). It would have been obvious to one of ordinary skill in the art to modify the intervention of Katsumata'149 for the use of high frequency ultrasound because of the easy handling and simple manufacture (Col. 3, Line 37-40). Katsumata'149 teaches the interface device being removably attachable to

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the scan head (Col. 4, Line 21-26). Katsumata'149 teaches an interface device comprising a reservoir with a proximal end and a distal end (Figure 4A, Elements 11 & 15). Katsumata'149 teaches the proximal end being open (Figure 4A, Element 15). Katsumata'149 teaches shaped to allow the transducer to transverse across an intended scan path within said reservoir (Col. 11, Line 24-40). Katsumata'149 teaches the distal end extending past a distal end of the transducer (Figure 5, Element 12 & 18) and including a scan window through which ultrasound energy is transmitted and received (Col. 4, Line 20-26). Katsumata'149 teaches the reservoir maintaining a fluid tight seal around the transducer (Col. 9, Line 1-10) and a fluid coupling medium located within the reservoir (Figure 4A, Element 17).

Claim 2/1: Katsumata'149 teaches the interface device being sterile (Col. 5, Line 47-53).

Claim 3/1: Katsumata'149 teaches a device wherein the scan window is formed of a material with less than 1 db/mm signal loss of transmitted and received high frequency ultrasound (Col. 8, Line 9-15). Katsumata'157 teaches how to achieve low ultrasound attenuation.

Claim 4/1: Katsumata'149 teaches the scan window comprising a non-flowable hydrogel (Figure 5, Element 17 & 21).

Claim 5/1: Katsumata'149 teaches the scan window comprises a non-flowable hydrogel and a porous support structure (Figure 8B, Elements 63 & 57 and Element 63).

Claim 6/4/1: Katsumata'149 teaches the hydrogel comprising a crosslinked polymer with water content greater than or equal to 50% by weight (Col. 8, Line 9-15).

Claim 7/4/1: Katsumata'149 teaches the hydrogel comprising polyethylene oxide (Col. 4, Line 10-12).

Claim 9/1: Katsumata'149 teaches the length of the device past the transducer is adjustable to allow adjustment of the position of the transducer focus (Col. 11, Line 52-58). Katsumata'149 explains that the device is capable of movement in relation to the ultrasonic probe and ultrasonic coupler.

Claim 11/1: Katsumata'149 teaches a device wherein the distal end of the device is curved to approximate the radius of the eye (Col. 4, Line 45-51).

Claim 12/1: Katsumata'149 teaches a device wherein the reservoir comprises one or more separate pieces between which is disposed the hydrogel scan window (Figure 4A, Element 16 & 11).

Claim 13/1: Katsumata'149 teaches a device incorporating delivery of acoustic coupling material (Figure 8B, Element 63).

Claim 15/1: Katsumata'149 teaches a device that incorporates access for surgical instruments (Figure 7). The device of Katsumata'195 does not require an eyecup for operation and thus allows for access for surgical instruments as applicant stated that an eyecups is cumbersome and limits the use of ultrasound imaging during surgical procedures.

Claim 18/2/1: Katsumata'149 teaches a device that is sterilized by ionizing radiation (Col. 5, Line 47-53).

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4. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata'195 (US Patent No. 5,078,149) and further in view of Matthews'123 (US Patent No. 3,939,123).

Claim 8/4/1: Katsumata'149 teaches an overview of hydrogel composition but does not elaborate regarding more specific compositions and types. However Matthews'123 teaches hydrogel formed from polyisocyanate terminated poly(alkrylene ether) polyols (Col. 2, Line 13-49). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata'149 and Matthews'123 in order to produce a hydrogel with high water absorbency (Col. 5, Line 1-6) because high water content reduces attenuation (Katsumata'195; Col. 8, Line 9-15).

5. Claim 10 & 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata'195 and further in view of Puech'855 (US Patent No. 6,837,855 B1).

Claim 10/1: Katsumata'149 fails to teach the focus range of the device. However, Puech'855 teaches a device wherein the transducer focus is in the range of 2 to 6 mm past the distal the edge of the device (Col. 6, Line 38-48). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata'149 and Puech'855 in order to for specific exploration of the anterior segment of the eye (Col. 6, Line 38).

Claim 14/1: Katsumata'149 fails to teach wherein the ultrasound frequency is in the range of 50 to 100 MHz (Col. 4, Line 41-50 & Col. 6, Line 38-48). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to

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combine the teachings of Katsumata'149 and Puech'855 in order to have better image resolution (Col. 2, Line 15-18).

6. Claim 16 & 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsumata'149 and further in view of de Juan'335 et al. (US Patent Application No. 2001/0029335 A1).

Claim 16/1: Katsumata'195 fails to teach the surgical instrument. However, de Juan'335 teaches the device incorporating a surgical instrument (Figure 5A, Element 305a & 206, Figure 6A & 6B and Page 4, Paragraph 0042). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata'149 and de Juan'335 in order for a surgeon to scan the retina during the procedure to evaluate the effectiveness of the action taken (Page 4, Paragraph 0046).

Claim 17/1: Katsumata'195 fails to teach the surgical instrument. However, de Juan'335 teaches the device wherein the device incorporates a surgical instrument that allows use of the instrument in positional relationship to the scanned image (Page 1, Paragraph 0010). It would have been obvious to one of ordinary skill in the art at the time of the invention was made to combine the teachings of Katsumata'149 and de Juan'335 in order to better plan the surgical approach and provide high resolution images.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. Iezzi, Raymond. Scanning Control System for Ultrasound Biomicroscopy. US Patent No. 5,551,432. September 3, 1996.
- b. Mayol, Jean-Claude et al. Sealed Magnetic Drive Means without a Passage through a Wall and Ultrasound Probe Comprising an Application Thereof. US Patent No. 5,357,963. October 25, 1994.
- c. Saied, Amena et al. Method for Exploring and Displaying Tissue of Human or Animal Origin from a High Frequency Ultrasound Probe. US Patent No. 6,949,071 B1. September 27, 2005.
- d. Sakane, Toshio. Cornea Thickness Measuring Ultrasonic Probe. US Patent No. 4,823,801. April 25, 1989.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helene Bor whose telephone number is 571-272-2947. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

hcb

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